IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

SUSAN SWICEGOOD, Plaintiff, v. PLIVA, INC., et al., Defendants.	CIVIL ACTION FILE NO. 1:07-CV-1671-TWT

ORDER

This is a personal injury case. It is before the Court on the Defendant Barr Pharmaceuticals, Inc.'s Motion for Summary Judgment [Doc. 75], the Defendant Pliva, Inc.'s Motion for Summary Judgment [Doc. 77], the Defendants' Motion to Strike the Expert Reports and Exclude the Testimony of Plaintiff's Expert Witnesses [Doc. 76], and the Plaintiff's Motion to Strike Expert Reports and Exclude the Testimony of Defendants' Expert Witnesses [Doc. 88]. For the reasons stated below, Barr's Motion for Summary Judgment [Doc. 75] is GRANTED, Pliva's Motion for Summary Judgment [Doc. 77] is GRANTED in part and DENIED in part, the Defendants' Motion to Strike the Expert Reports and Exclude the Testimony of Plaintiff's Expert Witnesses [Doc. 76] is DENIED, and the Plaintiff's Motion to Strike

Expert Reports and Exclude the Testimony of Defendants' Expert Witnesses [Doc. 88] is DENIED.

I. Background

In 2005, Plaintiff Susan Swicegood was diagnosed with dyspepsia and gastroesophageal reflux disease. Her primary-care physician, Dr. Michael Reese, treated Swicegood with metoclopramide ("MCP"), the generic form of Reglan. MCP is approved by the FDA for the short-term treatment of gastroesophageal reflux disease. Swicegood alleges that she developed tardive dyskinesia, a movement disorder consisting of involuntary muscle contractions, from her use of MCP. She sued Pliva, Inc. and Barr Pharmaceuticals, Inc. on strict liability, negligence, and breach of warranty theories.

II. Discussion

A. Motions to Exclude Expert Testimony

1. Standard

Under Rule 26 of the Federal Rules of Civil Procedure, "a party must disclose to the other parties the identity of any witness it may use at trial to present evidence under [the expert witness rules]." Fed. R. Civ. P. 26(a)(2)(A). This disclosure must be accompanied by a written report, and the written report must contain, among other things, "a complete statement of all opinions the witness will express and the basis and

reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). The reason for the expert disclosure rule is "to provide opposing parties reasonable opportunity to prepare for effective cross-examination and perhaps arrange for expert testimony from other witnesses." Reese v. Herbert, 527 F.3d 1253, 1265 (11th Cir. 2008). "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness ... unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

After identifying her expert witnesses, the Plaintiff was late in providing expert reports. The Defendants have not shown substantial prejudice to their ability to defend the case on the merits. The parties were unable to schedule discovery depositions of the Defendants' experts within the discovery period. The Defendants offered to make their experts available for discovery after the expert discovery deadline. The Plaintiff should have accepted the offer. Life is too short to try to say more.

B. Pliva's Motion for Summary Judgment

1. Summary Judgment Standard

Summary judgment is appropriate only when the pleadings, depositions, and affidavits submitted by the parties show that no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

The court should view the evidence and any inferences that may be drawn in the light most favorable to the nonmovant. Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970). The party seeking summary judgment must first identify grounds that show the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986). The burden then shifts to the nonmovant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact does exist. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986).

2. Statute of Limitations

Swicegood filed her complaint on July 19, 2007. Pliva says that the statute of limitations bars her claims. Personal injury actions in Georgia must be brought within two years after the cause of action accrues. O.C.G.A. § 9-3-33. A cause of action accrues when, in the exercise of reasonable diligence, the plaintiff discovers or should discover that she has been injured and that her injury was caused by the defendant's conduct. Harrison v. Digital Equipment Corp., 219 Ga. App. 464, 465 (1995). Whether the Plaintiff exercised reasonable diligence in discovering her injury and the cause thereof is a jury question.

In Piedmont Pharmacy, Inc. v. Patmore, 144 Ga. App. 160 (1977), the plaintiff suffered from steroid-induced glaucoma. She visited an opthamologist because she was having eye trouble and believed it may be connected to a medication she was

taking. The doctor told her that the medication was not causing her eye trouble and instead suggested a change in corrective lenses. Eventually, she visited another doctor who concluded that her medication probably was causing her condition. In a suit against the pharmacy who filled her prescription, the parties disputed when the statute of limitations began to run. The pharmacy argued that the statute began to run when the plaintiff visited the first doctor because she suspected at the time that her condition may have been caused by the medication. The plaintiff argued that the statute began to run when the second doctor told her that her medication probably caused her condition. The court held that the question of when the plaintiff should have discovered that her condition was caused by her medication was a question of fact for the jury. Id. at 162; see also Stephen W. Brown Radiology Associates v. Gowers, 157 Ga. App. 770, 773-74 (1981) (holding that "a patient has the right to believe what he is told by his medical doctors about his condition" but submitting the question of whether plaintiff exercised ordinary care in discovering the cause of his injury to the jury).

The facts here are similar to those in Piedmont Pharmacy. On July 18, 2005, Swicegood began experiencing neck pain. (Pliva's Mot. for Summ. J., Ex. 7 at 7a.) She called Dr. Michael Reese, her primary care physician, to ask if her neck pain could be related to her MCP use. His assistant said that MCP could have caused her

neck pain and told her to stop taking it. She told Swicegood to come into the office if her symptoms continued. (Id.) Two days later, Swicegood visited Dr. Reese, who concluded that her pain was orthopaedic in nature and unrelated to her MCP use. (Id., Ex. 7 at 7.) On July 29, she saw a chiropractor who disagreed and told her that her symptoms were probably caused by MCP. (Id., Ex. 3 at 91.) As in Piedmont Pharmacy, the issue of when Swicegood should have discovered that MCP caused her condition is a question of fact for the jury. A reasonable juror could find that the statute of limitations began to run on July 18, July 29, or sometime in between. Accordingly, Pliva is not entitled to summary judgment on statute of limitation grounds.

3. Learned Intermediary Doctrine

Pliva says that Swicegood's physician, Dr. Reese, was an adequately-warned learned intermediary whose involvement bars Swicegood's failure-to-warn claim. Under Georgia law, a drug manufacturer must adequately warn the "learned intermediary" – typically the prescribing physician – of risks associated with a prescription drug. McCombs v. Synthes, 277 Ga. 252, 253 (2003). The manufacturer has no separate duty to warn the patient. Id. For a warning to be adequate, it must disclose "the existence and extent of the risk involved." See Thornton v. E.I. Du Pont De Nemours and Co., Inc., 22 F.3d 284, 289 (11th Cir. 1994) (applying Georgia law).

Here, Pliva provided warnings that MCP could cause tardive dyskinesia, and Dr. Reese said that he knew about this risk. (Pliva's Mot. for Summ. J., Ex. 1, Ex. 9 at 53 - 54.) However, Swicegood argues, and a reasonable juror could infer, that Dr. Reese did not know the extent of the risk involved. (See id., Ex. 9 at 57 ("The chances of it being permanent would be very, very rare.").) Therefore, Pliva is not entitled to summary judgment based on the learned intermediary doctrine.

4. Causation

In products liability cases involving drug side effects, the plaintiff has the burden of showing general and specific causation. General causation is the connection between the drug and injuries of the kind suffered by the plaintiff. Specific causation is the connection between the drug and the plaintiff's actual injury. Like in all tort cases, the plaintiff also must show that the defendant's actions were the proximate cause of her injury. Pliva says that Swicegood has failed to establish any of these.

Swicegood's expert, Dr. Robert Nelson, says that MCP increases the risk of tardive dyskinesia above the background rate that exists in the general population when the drug is used for more than twelve weeks. In this case, Dr. Reese prescribed 60 tablets of Reglan. (Pliva's Mot. for Summ. J., Ex. 2 at 4.) He told Swicegood to take four tablets a day. He marked the prescription "PRN," which allowed Swicegood to refill the prescription as needed without his approval. (Id., Ex. 10.) She refilled it

three times, receiving a total of 240 tablets. (Id., Ex. 2 at 4.) If she had taken four tablets a day, the medication would have lasted just over eight weeks. However, Swicegood says that Dr. Desai, her gastroenterologist, told her to take two tablets a day and to try to wean herself off the medication. According to Swicegood, the 240 tablets lasted for at least fifteen weeks. Therefore, Dr. Nelson's testimony about the long-term use of MCP precludes summary judgment on general causation grounds.

Swicegood's neurologist, Dr. Factor, says that she has tardive dyskinesia caused by MCP. Pliva says that an expert may not give opinion testimony regarding specific causation if the expert has not performed a "differential diagnosis." A differential diagnosis is "a patient specific process of elimination that medical practitioners use to identify the most likely cause of [an injury] from a list of possible causes." Hawkins v. OB-GYN Assocs., P.A., 290 Ga. App. 892, 893 (2008). Pliva says that Dr. Factor did not do this. However, Dr. Factor explained in his deposition why he ruled out stiff person syndrome, idiopathic dystonia, and other conditions that can cause similar symptoms. (Pliva's Mot. for Summ. J., Ex. 16 at 24.) He also explained that blood tests were not available to confirm his diagnosis of tardive dyskinesia but said that he administered clinical tests to eliminate other possible causes. (Id. at Ex.

16 at 13.) Therefore, Dr. Factor's diagnosis is sufficiently reliable to support his opinion as to specific causation and create a genuine issue of fact for the jury.

Pliva next argues that Swicegood cannot show that its actions caused her injury because there is no evidence that Dr. Reese read the generic drug's label. Dr. Reese says that he read Reglan's label. Typically, a generic drug's label is the same as the corresponding name-brand drug's label. If a generic drug manufacturer wants to add or strengthen a warning, it may change its label before receiving formal FDA approval, as discussed below. In that case, the generic drug's label may be different from the name brand drug's label while the FDA approves and implements the change. Still, a reasonable juror could infer that if a generic drug changed its label through this process, a physician who prescribed the drug on a regular basis would have learned of the change and read the package insert for the generic drug. Therefore, Dr. Reese's reliance on the Reglan label instead of the generic MCP label does not entitle Pliva to summary judgment.

5. Punitive Damages Claim

Pliva says that Swicegood is not entitled to punitive damages. Under Georgia law, punitive damages are available where "the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A.

§ 51-12-5.1(b). Swicegood says that punitive damages are appropriate because Pliva knew that MCP could cause tardive dyskinesia and failed to take appropriate steps to investigate or report the risk. She cites Dr. Nelson's expert report, which summarizes scientific studies dating back several decades that suggest that the risk of tardive dyskinesia is significantly higher than that suggested on Pliva's label. (See Pl.'s Resp. to Defs.' Mot. to Exclude Expert Testimony, Ex. D.) Based on this information, a reasonable juror could conclude that Pliva acted "wantonly" or "with conscious indifference" by failing to warn patients about this risk. Therefore, Pliva is not entitled to summary judgment on Swicegood's punitive damages claim.

6. Design Defect Claim

Under Georgia law, "a manufacturer has a duty to exercise reasonable care in manufacturing its products so as to make products that are reasonably safe for intended or foreseeable uses." Chrysler Corp. v. Batten, 264 Ga. 723, 724 (1994). To determine whether a product is defective as designed, the risks inherent in the product's design are balanced against the utility derived from the product. Banks v. ICI Americas, Inc., 264 Ga. 732, 734 (1994). In some cases, a product is incapable of being made safe for its intended and ordinary use. In those cases, Georgia courts follow § 402, Comment K, of the Restatement (Second) of Torts, which provides an affirmative defense for manufacturers of unavoidably unsafe products. Under

Comment K, a manufacturer will be relieved of liability if it shows that "(1) the product [was] properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe." Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 406 (2003). Whether the risks of a product outweigh its benefits and whether the defendant is relieved of liability under Comment K are questions for the jury. Id. at 409.

Pliva argues that it is entitled to summary judgment on Swicegood's design defect claim because she has not presented evidence of a safer alternative design for MCP. However, the court in Bryant made clear that the absence of a safer alternative design is an affirmative defense. Accordingly, the burden is on Pliva to show that MCP cannot be made safer. Therefore, Pliva is not entitled to summary judgment on Swicegood's design defect claim.

7. Express and Implied Warranty Claims

To assert a breach of warranty claim, the plaintiff generally must be in privity with the seller of the allegedly defective product. Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 410-11 (2003). This means that the defendant must have sold the product directly to the plaintiff. Limited exceptions exist, but none apply here. See O.C.G.A. § 11-2-318 (extending a seller's warranty to limited third-party

beneficiaries). Accordingly, because Pliva did not sell MCP directly to Swicegood, she cannot recover on her breach of warranty claims.

8. Preemption

Pliva says that Swicegood's state-law failure-to-warn claim is preempted by FDA regulations. State law is deemed preempted where there is a direct conflict between federal and state law or where state law interferes with the achievement of a federal objective. See Florida Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963); Hines v. Davidowitz, 312 U.S. 52, 67 (1941). The Supreme Court has directed courts to start with the presumption that state law is not preempted and find preemption only where it is "the clear and manifest purpose of Congress." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

a. Conflict Preemption

All prescription drugs marketed in the United States must receive FDA approval. 21 U.S.C. § 355(a). Manufacturers of new drugs must submit a new drug application (NDA) to the FDA. An NDA must show that the drug is effective and safe for its intended use and that its labeling accurately describes the risks and benefits of treatment. Under the Hatch-Waxman Act, manufacturers of generic drugs may receive FDA approval through a simpler process known as the abbreviated new drug application (ANDA) process. See 21 U.S.C. § 355(j). To qualify for ANDA, a

generic drug must be the "same as" a name-brand drug that has already been approved. Id. The proposed label must also be the same. Id. Pliva says that because FDA regulations require a generic drug's label to be the same as the name-brand drug's label, it cannot simultaneously comply with FDA regulations and its state-law duty to warn.

Although a generic drug's label must be the same as the name-brand drug's label when it is approved, most courts have held that a generic manufacturer may strengthen label warnings after a drug is approved through a Changes Being Effected ("CBE") supplement. See Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010); Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994); Munroe v. Barr Labs., Inc., No. 4:07-cv-395, 2009 WL 4047949 (N.D. Fla. Oct. 15, 2009); Bartlett v. Mutual Pharm. Co., 659 F. Supp. 2d 279 (D.N.H. 2009); Stacel v. Teva Pharm., USA, 620 F. Supp. 2d 899 (N.D. Ill. 2009); Kellogg v. Wyeth, 612 F. Supp. 2d 437 (D. Vt. 2009); Barnhill v. Teva Pharm., 06-0282-CB-M, 2007 WL 6947996 (S.D. Ala. April 24, 2007); Laisure-Radke v. Par Pharm., Inc., No. CO3-365RSM, 2006 WL 901657 (W.D. Wash. Mar. 29, 2006). But see Gaeta v. Perrigo Pharm. Co., No. C 05-04115, 2009 WL 4250690 (N.D. Cal. Nov. 24, 2009) (holding that CBE changes are not available for generic drugs approved under an ANDA); Morris v. Wyeth, Inc., 642 F. Supp. 2d 677 (W.D. Ky. 2009) (same). The CBE process allows

drug manufacturers to add or strengthen label warnings based on newly acquired information before receiving formal FDA approval for the changes. 21 C.F.R. §§ 314.70(c). Pliva argues that generic drug companies cannot use this process. It cites statements by the FDA suggesting that the process is limited to name-brand manufacturers. This argument seems inconsistent with the clear language of 21 C.F.R. §§ 314.70(c) and 314.97. Section 314.70(c) expressly authorizes drug manufacturers to strengthen label warnings through the CBE process, and Section 314.97 directs generic manufacturers to comply with § 314.70.

However, even if the CBE process is limited to name-brand manufacturers, generic manufacturers may effect label changes in other ways. See Demahy, 593 F.3d at 444-45; Mensing v. Wyeth, 588 F.3d 603, 608-611 (8th Cir. 2009) (holding that state-law failure-to-warn claim against generic manufacturer is not preempted by federal law). For example, they may propose a label change under 21 C.F.R. § 314.70(b)(2)(v)(A) that the FDA could review and impose uniformly on all MCP manufacturers. See 21 C.F.R. § 314.70(b)(2)(v)(A) (describing approval process for label changes not effected through the CBE process); see also 57 Fed. Reg. 17950, 17961 cmt. 40 (Apr. 28, 1992) ("After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the

generic and listed drugs should be revised."). They may also suggest that the FDA send out a warning letter to healthcare professionals alerting them of newly acquired information about the risks of a drug. Demahy, 593 F.3d at 444-45; Mensing v. Wyeth, 588 F.3d 603, 610 (8th Cir. 2009). Finally, if generic manufacturers believe their label is inadequate but do not believe they can even propose a label change, they can stop selling the drug altogether rather than marketing an allegedly dangerous drug without adequate warnings. Mensing, 588 F.3d at 611. Therefore, because Pliva had several means of complying with both federal and state law, Swicegood's state-law failure-to-warn claim is not preempted on conflict grounds.

b. Preemption Based on Interference with Federal Objectives

Pliva next argues that compliance with Georgia law will impose "enormous expense" on generic manufacturers by requiring them to conduct studies and clinical trials to generate new data on drug risks. According to Pliva, these costs would increase the market price of generic drugs and impede Congress's objective of making low cost generic drugs available through the ANDA approval process.

Pliva's argument is based on the assumption that generic manufacturers would be required to justify label changes through their own clinical trials and studies. However, "[w]hile clinical studies . . . may be used to support labeling changes, they are in no way prerequisites to those changes." Demahy, 593 F.3d at 447. For

example, when the FDA mandated an enhanced warning for MCP in 2009, it did not rely on studies by Reglan or generic MCP manufacturers. Instead, it referenced studies published elsewhere. Id. at 447. Indeed, Pliva presents no persuasive evidence that requiring generic manufacturers to satisfy a state-law duty to warn would impose significant financial burdens on generic manufacturers and drive up the cost of generic drugs.

Moreover, federal preemption of state-law failure-to-warn claims would entirely deprive generic drug users of a remedy afforded to brand-name drug users under Wyeth v. Levine, 129 S. Ct. 1187 (2009), in which the Supreme Court held that state-law failure-to-warn claims against brand-name manufacturers are not preempted. The Fifth Circuit explained:

> Unless the law would somehow harness liability onto name brand manufacturers for all failure-to-warn claims, preemption in this case would leave [the plaintiff] without a remedy. Yet, if Congress had intended to deprive [the plaintiff] of a long available form of compensation, it surely would have expressed that intent more clearly. To hold otherwise would leave us with the bizarre conclusion that Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of any remedy, while under Levine, the same plaintiff would have a state-law claim had she only demanded a name brand drug instead.

Demahy, 593 F.3d at 449. Based on these considerations, I cannot conclude that it was the "clear and manifest purpose" of Congress to preempt state law. Accordingly, Pliva is not entitled to summary judgment on preemption grounds.

C. Barr Pharmaceuticals' Motion for Summary Judgment

Pliva is an indirect wholly-owned subsidiary of Barr Pharmaceuticals, Inc. Barr says that it is not and has never been a manufacturer or seller of MCP and that it is not the successor-in-interest of Pliva, as alleged by the Plaintiff. (See Barr's Mot. for Summ. J., Ex. 2 at 2.) Therefore, Barr argues that it is not liable on strict liability, negligence, or breach of warranty theories. (See April 2 Order [Doc. 49] (dismissing claims against Wyeth and Schwarz because they did not manufacture MCP ingested by the plaintiff).) Swicegood has not responded to Barr's Motion for Summary Judgment or produced any evidence supporting her allegation that Barr is the successor-in-interest of Pliva. Therefore, Barr is entitled to summary judgment.

III. Conclusion

For the reasons stated above, Barr's Motion for Summary Judgment [Doc. 75] is GRANTED, Pliva's Motion for Summary Judgment [Doc. 77] is GRANTED in part and DENIED in part, the Defendants' Motion to Strike the Expert Reports and Exclude the Testimony of Plaintiff's Expert Witnesses [Doc. 76] is DENIED, and the Plaintiff's Motion to Strike Expert Reports and Exclude the Testimony of Defendants' Expert Witnesses [Doc. 88] is DENIED. The Motion for Oral Argument [Doc. 98] is DENIED.

SO ORDERED, this 15 day of March, 2010.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge